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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/762,045	09/17/2001	Andrea Reindl	817/000006	7926

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EXAMINER	
KALLIS, RUSSELL	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 06/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/762,045	REINDL ET AL.	
	Examiner	Art Unit	
	Russell Kallis	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 March 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

It appears that Applicant has inadvertently stated in the remarks filed 3/08/2005 that Claims 1-22 are pending and Claims 5-8, 11-12, 15-16 and 20-22 are withdrawn. However, the claims filed 3/08/2005 show Claims 1-22 are canceled and new claims 23-34 have been filed and are currently pending. In the interests of compact prosecution the Examiner will examine newly submitted Claims 23-34 drawn to the elected sequence of SEQ ID NO: 1.

The rejection of Claims 1-4 under 35 U.S.C. 112, second paragraph is withdrawn in view of Applicant's amendment.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 23-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 10/06/2004. Applicant's arguments filed 3/07/2005 have been considered but are not deemed persuasive.

Applicant asserts that the claimed subject matter relates to a method for producing a plant that has increased tocopherol, vitaminK, chlorophyll and/or carotenoid content and that the subject of *Lily* does not pertain to the description of DOXS and HPPD sequences of the instant application because *Lily* pertains to recombinant plasmids and the encoded protein and not methods requiring those DNA or protein sequences (response pages 3-4). The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. The court stated that, "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." *See University of California v. Eli Lilly and Co.*, 119 F.3d 1559; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). Furthermore, Applicants fail to describe structural features common to members of the claimed genus of DOXS and HPPD encoding sequences. Hence, Applicants fail to meet either prong of the two-prong test set forth by *Eli Lilly*. Furthermore, given the lack of description of the necessary elements essential for DOXS or HPPD activity, it remains unclear what features identify a DOXS or HPPD encoding DNA sequence. Since the genus of DNA sequences encoding a protein having DOXS activity or HPPD activity has not been described by specific structural features, the specification fails to provide an adequate written description to support the breath of the claims. Moreover, given the failure of the claimed genus of DOXS and HPPD encoding sequences to be adequately described, methods of their use are also inadequately described. See Written Description

Guidelines, Federal Register Vol. 66 No. 4, Friday January 5, 2001 "Notices", pages 1099-1111.

Applicant asserts that since the specification recites references that teach how to assay for DOXS or HPPD activity thereby verifying the identity of a particular cDNA sequence the written description requirement has been met (response pages 4-5). See arguments presented supra stating that in order for a genus to be described Applicant's must describe specific structural features of the claimed genus or genera.

Claims 23-26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the use of SEQ ID NO: 1; and SEQ ID NO: 1 and SEQ ID NO: 5 together for producing plants that have increased tocopherol, vitamin K, chlorophyll, and/or carotenoids; and a method for producing plants with increased tocopherol, vitamin K, chlorophyll, and/or carotenoids which express SEQ ID NO: 1 or both SEQ ID NO: 1 and 5, does not reasonably provide enablement for the use of any sequence that hybridizes to SEQ ID NO: 1 or SEQ ID NO: 5 and encodes a DOXS or HPPD or any DOXS or HPPD encoding polynucleotide; or a method of increasing tocopherol, vitamin K, chlorophyll, and/or carotenoids in a plant which expresses any sequence that hybridizes to SEQ ID NO: 1 or SEQ ID NO: 5 and encodes a DOXS or HPPD or any plant transformed with an expression cassette which expresses any DOXS or DOXS and HPPD other than SEQ ID NO: 1 or SEQ ID NO: 5. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. This rejection is maintained for the reasons of record set forth in the Official action

mailed 10/06/2004. Applicant's arguments filed 3/07/2005 have been considered but are not deemed persuasive.

Applicant asserts that the claimed subject matter is directed to a method for using genes that encode DOXS or HPPD enzymes for producing transgenic plants having altered metabolite levels and that none of the claims are drawn to unknown DNA sequence encoding either a DOXS ro HPPD proteins from any source (response page 5). Actually the claims are drawn to methods of increasing tocopherol, vitamin K, chlorophyll, and/or carotenoids in a plant which expresses any sequence that hybridizes to SEQ ID NO: 1 or SEQ ID NO: 5 and encodes a DOXS or HPPD or any plant transformed with an expression cassette which expresses any DOXS or DOXS and HPPD. Clearly, the claimed sequence other than SEQ ID NO: 1 and 5 are unknown because they have not been isolated or described by the art or Applicant's specification.

Applicant asserts that does not understand why one of ordinary skill in the art would have to undergo undue experimentation to make and use the present invention (response page 6 second paragraph). Given the lack of guidance in the instant specification, undue trial and error experimentation would be required for one of ordinary skill in the art to screen through a multitude of non-exemplified sequences, either by using SEQ ID NO: 1 and 5 as probes, and isolating or amplifying fragments, subcloning the fragments, producing expression vectors and transforming plants therewith, in order to identify those polynucleotides that when expressed have DOXS or HPPD activity and produce plants with increased content of tocopherols, vitamin K, chlorophyll, and/or carotenoids.

Claim Rejections - 35 USC § 102

Claims 23-24 and 27-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Mandel M. *et al.* Plant Journal, 1996; Vol. 9, No. 5, pp. 649-658 in light of Estevez J. *et al.* Plant Physiology, September 2000; Vol. 124, pp. 95-103 and the attached sequence report. This rejection is maintained for the reasons of record set forth in the Official action mailed 10/06/2004. Applicant's arguments filed 3/07/2005 have been considered but are not deemed persuasive.

Applicant asserts that the Estevez reference was not published more than one year prior to the date of application of the invention at hand (9/17/2001) and thus cannot form the basis for a rejection under 35 U.S.C. 102(b) (response page 7). Estevez teaches that CLA1 encodes a 1-deoxyxylulose-5-phosphate synthase of SEQ ID NO: 1 showing that Mandel taught inherently SEQ ID NO: 1 in the article published in 1996; see also pages 653 and 654 of Mandel.

Applicant asserts that Estevez is not prior art under 103(a) because it was not published more than one year prior to the date of application of the invention at hand and because Mandel does not teach levels of expression above the wild type or overcoming metabolic bottlenecks and that overproduction will not necessarily lead to greater than wild type levels of metabolites (response page 7, second paragraph and page 8). Estevez is prior art for the purposes of a rejection under 35 U.S.C 103(a) to the extent that it was presented in the rejection under 35 U.S.C. 102(b) in light of Mandel to show that the CLA1 sequence of Mandel is SEQ ID NO: 1. Further, Applicants argument that above wild type levels are not present in the phenotype taught by Mandel is not reflected in the claims which do not mention increases above wild type levels only increases.

Claim Rejections - 35 USC § 103

Claims 23-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mandel M. *et al.* Plant Journal, 1996; Vol. 9, No. 5, pp. 649-658 in view of Dellapenna D. WO 97/27285 published July 31, 1997; and in further view of Estevez J. *et al.* Plant Physiology, September 2000; Vol. 124, pp. 95-103. This rejection is maintained for the reasons of record set forth in the Official action mailed 10/06/2004. Applicant's arguments filed 3/07/2005 have been considered but are not deemed persuasive.

Applicant asserts that there is no motivation to combine the teachings of Mandel and those of Dellapena (response pages 8-9). One of skill in the art would have been motivated by the knowledge common in the art that isoprenoid products (i.e. tocopherols, vitamin K, chlorophyll, and carotenoids) are important in the production of plant pigments as taught by Mandel, and because the genes encoding DOXS and HPPD synthesize the precursors to tocopherols, vitamin K, chlorophyll, and carotenoids, are recognized in the art for their value for genetically engineering plants to increase the levels of those plant isoprenoid derived compounds also taught by Dellapenna; and that DOXS and HPPD genes were available in the art as taught by Applicant's specification and by Dellapenna; that one would have had a reasonable expectation of success of transforming plants with DOXS and HPPD genes and success in selecting for transformed plants having increased levels of tocopherols, vitamin K, chlorophyll, and/or carotenoids given the success of Mandel; wherein combining two transgenes into one plant and wherein choosing soybean, canola, barley, oats, wheat, oilseed rape, corn or sunflower as a target species is an obvious design step given the lack of criticality.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (571) 272-0798. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Russell Kallis Ph.D.
May 18, 2005

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